

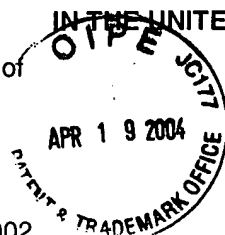
61
In re Patent Application of

KWOK et al.

Serial No. 10/068,963

Filed: February 11, 2002

Title: NASAL MASK AND MASK CUSHION THEREFOR



Atty Dkt. 4398-224

C# M#

TC/A.U.

3761

Examiner: Darwin P. Erez

Date: April 19, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.**

Fees are attached as calculated below:

Total effective claims after amendment 77 minus highest number
previously paid for 77 (at least 20) = 0 x \$ 18.00 \$ 0.00

Independent claims after amendment 14 minus highest number
previously paid for 14 (at least 3) = 0 x \$ 86.00 \$ 0.00

If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper) \$ 0.00

Petition is hereby made to extend the current due date so as to cover the filing date of this
paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months) \$ 110.00

Terminal disclaimer enclosed, add \$ 110.00 \$ 0.00

☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00) \$ 0.00

☐ Please enter the previously unentered , filed

☐ Submission attached

Subtotal \$ 110.00

If "small entity," then enter half (1/2) of subtotal and subtract -\$ 0.00

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee (\$180.00) \$ 0.00

Assignment Recording Fee (\$40.00) \$ 0.00

Other: 0.00

TOTAL FEE ENCLOSED \$ 110.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
By Atty: Paul T. Bowen, Reg. No. 38,009

Signature: 



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

KWOK et al.

Atty. Ref.: 4398-224; Confirmation No. 2378

Appl. No. 10/068,963

TC/A.U. 3761

Filed: February 11, 2002

Examiner: Darwin P. Erez

For: NASAL MASK AND MASK CUSHION THEREFOR

* * * * *

April 19, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST FOR RECONSIDERATION

In response to the Official Action dated December 17, 2003 (for which petition is hereby made for a one month extension of time), Applicants respectfully request reconsideration and withdrawal of the final rejection in view of the following remarks.

Claims 23-32 remain rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 5,647,357 to Barnett et al. This rejection is respectfully traversed.

Independent claim 23 is directed to a nasal mask cushion to sealingly connect a mask to a wearer's face. The cushion comprises a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose; a membrane also of resilient material ... and extending away from the frame so as to have an outer surface

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..., a portion of the outer surface forming a face contacting seal portion; and a nose receiving cavity bounded by the frame and the membrane. The face contacting seal portion is generally coterminous with respect to the rim and is resiliently deformable towards the rim in use with the cushion.

Barnett et al. does not teach or suggest this subject matter. In particular, Barnett et al. does not teach or disclose a nasal mask cushion which has a frame, a membrane and a nose receiving cavity as recited in claim 23. Barnett et al. teaches a respiratory mask 10 including a shell or body portion 12 having an open side 14 that defines an annular surface 16 to which is sealingly affixed a facial seal 18. Column 4, lines 30-35. The facial seal 18 is the only element in Barnett et al. which qualifies as a nasal mask cushion, per claim 23. However, the facial seal 18 does not include a frame, a membrane and a nose receiving cavity as recited in claim 23. In fact, the Office Action indicates that the Barnett et al. frame is element 12 (i.e., the shell or body portion), which is not part of the cushion or facial seal 18.

Further, Barnett et al. does not teach a frame of resilient material, per claim 23. Instead, Barnett et al. indicates that the mask body portion 12 is preferably, although not necessarily, a generally rigid formed structural shell. Column 4, lines 37-39. In contrast, Barnett et al. describes the facial seal as an elastic, resilient, unitary member. Column 4, lines 39-40. Thus, Barnett et al. contrast the material make-up of the body portion 12 and the facial seal 18, one being a generally rigid form structural shell while the other is a flexible resilient unitary member.

It is also noted that claim 23 recites that the membrane "... is also of resilient material, the membrane being relatively more flexible than the frame." Accordingly, the phrase "the membrane being relatively more flexible than the frame" imparts a certain amount of flexibility to the frame, since its flexibility is being measured in relation to the membrane. Thus, Applicants respectfully submit that claim 23 should be interpreted as meaning that the frame is also flexible. Body portion 12 is not flexible as it is a shell element, typically made of a rigid polycarbonate plastic material.

In addition, Applicants submitted a similar argument in relation to U.S. Patent Application No. 10/067,772, now U.S. Patent No. 6,581,602, which was also handled by Examiner Erez. In particular, the Examiner issued a rejection dated May 31, 2002 against claim 7 of the '772 application in view of Barnett et al. Claim 7 also recited "... a frame ... of resilient material" and the Examiner took the position that Barnett et al. taught this subject matter.

However, that rejection was withdrawn after an interview with the Examiner on July 2, 2002 in which it was agreed that Barnett et al. does not teach a frame of resilient material. The agreement was memorialized in the Amendment of July 15, 2002. In response to that traversal, the rejection of claim 7 based on Barnett et al. was withdrawn and replaced with a different rejection based on Sullivan et al.* See the Office Action dated September 30, 2002. Applicants respectfully submit that it is improper for the

* Ultimately, claim 7 was canceled in order to expedite allowance of the entire application.

Examiner to take up a different position of Barnett et al., especially as the Examiner has pointed to no new description within the disclosure of Barnett et al. to substantiate such a shift in positions.

Further, Barnett et al. does not teach or suggest that the face contacting seal portion is generally coterminous with respect to the rim, as recited in claim 23. In the Office Action, it is asserted that frame 12 has a rim. However, claim 23 defines the membrane as including an outer surface with a portion that forms a face contacting seal portion, and that the face contacting seal portion is generally coterminous with respect to the rim. By sharp contrast, Barnett et al. does not teach that the rim of the frame 12 is generally coterminous with the face contacting seal portion of the membrane or facial seal 18 of Barnett et al. The rim of the frame 12 and the face contacting seal portion of the facial seal 18 are at opposite sides of the facial seal 18.

Claims 24-31 are dependent on claim 23 and define additional features which distinguish over Barnett et al.

With respect to independent claim 32, Barnett et al. does not teach a nasal mask cushion assembly including a generally triangularly shaped frame of resilient material, a generally triangularly shaped membrane of resilient material, wherein the membrane is more flexible than the frame. Again, Barnett et al. includes a shell or body portion 12 which is not part of the facial seal 18. Accordingly, the Examiner's characterization that Barnett et al. includes a frame per claim 32 is clearly erroneous, as the shell or body portion 12 does not form a part of the facial seal or cushion 18. Moreover, Barnett et al.

does not teach that the facial seal 18 includes both a frame and a membrane, each of resilient material, wherein the membrane is more flexible than the frame. In addition, the facial seal 18 of Barnett et al. does not include a frame and membrane each having its own respective notch, as recited in claim 32.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 33 was rejected under 35 U.S.C. § 103(a) over Barnett et al. This rejection is traversed as claim 33 depends from claim 32, which is distinguishable from Barnett et al. for the reasons described above. In addition, Barnett et al. shows frame 12 and a membrane 18 formed of two different pieces. There is no disclosure in Barnett et al. that the frame and the membrane could be formed in a single piece. In fact, Applicants respectfully submit that it is unlikely that the frame and the membrane would be formed of one piece as the frame 12 is made of a rigid material while the facial seal 18 is made of a flexible, resilient material.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 34-39 were rejected under 35 U.S.C. § 103(a) over Barnett et al. in view of Sullivan et al.

At the outset, it is noted that Sullivan et al. is substantially as disclosed in Prior Art Figs. 1-3 and in the Background section of the present application. Moreover, Sullivan et al. does not make up for the deficiencies noted above with respect to Barnett et al. For example, neither Barnett et al. nor Sullivan et al. discloses a cushion which includes a

frame and a membrane, each of which includes a notch in a region adapted to receive the bridge of the wearer's nose. As discussed above, Barnett et al. only discloses a facial seal 18 having a monolithic design without a pair of notches, whereas Sullivan et al. has a membrane which is bubble-shaped and includes no notch. In addition, independent claims 36 and 38 are directed to nasal mask cushion assemblies including a frame and a membrane, each of which includes a notch in a region adapted to receive the bridge of the wearer's nose.

Claims 35, 37 and 39 recite that the frame of the membrane are formed in a single piece. As described above, Barnett et al. do not teach or disclose this subject matter. Sullivan et al. teaches that molding 27 in Fig. 5 might be configured to provide an element to a support for the membrane 13 or, in an alternative arrangement, the membrane might be formed integrally with the molding 27. However, as illustrated, the molding 27 is formed separately from the membrane 13 and includes an integral wall 36 which is profiled at region 37 to locate around the nasal bridge of the wearer 12 and at region 38 to fit against the upper lip of the wearer. See column 4, lines 56-68.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 23-39 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,357,441. In support of this rejection, the Office Action indicates that the structural limitations set forth in claims 23-39 are also claimed in the patent, and the Office Action

in paragraph 12 goes on to recite some common features between the application and patented claims.

Similarly, claims 40-99 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,513,526. Again, the Office Action provides a number of features which are common to both the application and patented claims.

According to MPEP § 804, a rejection based on obviousness-type double patenting should make clear:

A) the differences between the inventions defined by the conflicting claims, a claim in the patent compared to a claim in the application; and

B) the reasons why a person of ordinary skill in the art would conclude that the invention defined and the claim in issue is an obvious variation of the invention defined in a claim in the patent.

The Office Action has complied with neither requirement. No differences between the claims have been identified, and there is no statement of reasons why a person of ordinary skill in the art would conclude that the application claim is an obvious variation from the patented claim. Moreover, the Office Action has not applied the factual inquiries set forth in Graham v. John Deere, 383 US 1, 148 USPQ 459 (1966).

The MPEP summarizes these factual inquiries as follows:

(A) determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;

(B) determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;

(C) determine the level of ordinary skill in the pertinent art; and

(D) evaluate any objective indicia of non-obviousness.

Again, the Office Action provides no analysis in regard to any of the factual inquiries under Graham v. John Deere.

Instead, the Office Action simply indicates that there are many features in common between the application and patented claims. In the response section to Applicants' arguments, it is stated that "the rejected claims of the instant application are matched up with the claims from the parent patent and ... each limitation in the instant application are [sic] taught in the patent." It is further stated that "... the only difference between the claims in the instant application and the patent is how the functional language for each structure limitation is recited. However, each structural limitation rejected under double patenting is taught in a corresponding patent."

The analysis in the Office Action and the response to the arguments do not satisfy the steps which must be followed when making obviousness-type double patenting rejections, according to the MPEP.

For example, one difference between claim 1 of the '526 patent and claim 40 of the present application is that patent claim 1 recites a full face mask cushion comprising, *inter alia*, a nasal bridge region, a cheek region and a chin region. By contrast, claim 40 of the present application is directed to a nasal mask cushion including a nasal bridge

region, a cheek region and a lip region. Furthermore, claim 1 of the '526 patent recites that the second membrane curved rim is spaced a first distance from the first membrane curved rim in the cheek region and said second membrane curved rim is spaced a second distance from the first membrane curved rim in the nasal bridge region, said second distance being greater than the first distance.

By contrast, claim 40 does not recite these features. Instead, claim 40 recites that the second membrane curved rim is spaced a distance from the first membrane curved rim, said distance being greater than a thickness of the first molded inwardly curved rim.

Moreover, the differences between patented claims 1-25 of the '526 patent and application claims 40-99 are almost too numerous to list. The differences between application claims 23-39 and the '441 patent claims are almost too numerous to list as well. Accordingly, the rejections are in error and therefore the finality of the Office Action must be withdrawn.

Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.


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Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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